UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 15, 2024

Biora Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39334**	**27-3950390**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4330 La Jolla Village Drive, Suite 300 **San Diego, California** **(Address of Principal Executive Offices)**	**92122** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (833) 727-2841

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	BIOR	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
Emerging growth company
☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.
☐

Item 2.02 Results of Operations and Financial Condition.

On May 15, 2024, Biora Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2024. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

As provided in General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibit 99.1 incorporated herein shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall such information or Exhibit 99.1 be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release dated May 15, 2024
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Biora Therapeutics, Inc.

Date: May 15, 2024

By: /s/ Aditya P. Mohanty

Aditya P. Mohanty
Chief Executive Officer

Exhibit 99.1

Biora Therapeutics Provides Corporate Update and Reports First Quarter 2024 Financial Results

Dosing of all patients in clinical trial of BT-600 has been successfully completed, with results anticipated in late Q2 2024

Clinical data on device function of the NaviCap™ platform to be presented at DDW on May 19

Partnering process for the BioJet oral delivery platform is progressing well

Management will host conference call and webcast today at 4:30 PM Eastern / 1:30 PM Pacific

SAN DIEGO, May 15, 2024 – Biora Therapeutics, Inc. (Nasdaq: BIOR), the biotech company that is reimagining therapeutic delivery, today provided a corporate update and reported financial results for the first quarter ended March 31, 2024.

"We were gratified to see the excellent interim results from our clinical trial for BT-600, where we observed a pharmacokinetic profile consistent with drug delivery and absorption in the colon," said Adi Mohanty, Chief Executive Officer of Biora Therapeutics. "We recently announced completion of the remaining portion of the trial, in which a cohort of 24 healthy participants received BT-600 at 5 mg and 10 mg doses of tofacitinib, or placebo, with once daily dosing for seven days. We are now awaiting the analysis of those results, and we anticipate sharing full study data in late June. Everything we have seen so far reinforces our belief that the NaviCap™ platform could optimize JAK inhibitor therapy in ulcerative colitis and lead to improved efficacy and reduced toxicity for patients."

"We continue to progress our BioJet platform, with further animal studies in recent months that demonstrate advances in bioavailability and consistency with our own drug candidates and with collaborator molecules. We are currently running a partnering process for interested parties who see the potential for the BioJet platform and are eager to bring this technology to the clinic. Our goal is to confirm partner interest by mid-2024. We are encouraged by the engagement shown by some of our current collaborators, and we are also seeing strong interest from new companies," continued Mr. Mohanty.

First Quarter 2024 and Recent Highlights

NaviCap™ Targeted Oral Delivery Platform and BT-600 in ulcerative colitis

- **Completion of SAD Portion of Phase 1 Clinical Trial for BT-600.** Dosing of all participants in the trial has been successfully completed. Results from the single-ascending dose (SAD) portion of the trial were consistent with desired performance targets:
  - NaviCap devices were well tolerated by participants in the SAD cohort; no safety signals were observed.
  - All participants who received devices containing active drug showed systemic drug absorption, indicating that the NaviCap devices released and delivered drug

as intended. Tofacitinib was present in fecal samples of these participants, further confirming delivery of the drug in the colon.

- Measurable tofacitinib in blood was first observed at approximately six hours, with maximal concentrations at approximately eight hours post ingestion, which is indicative of drug delivery and absorption in the colon, as intended.
- Plasma levels of tofacitinib were approximately 3-4 times lower than what is observed with conventional oral tofacitinib at the same doses, which is a positive sign consistent with passage of drug through the colonic tissue and into systemic circulation.
- Dose-proportional pharmacokinetics were also observed, with consistently lower plasma drug concentrations with the 5 mg dose than the 10 mg dose.

BioJet™ Systemic Oral Delivery Platform preclinical development

- **BioJet Research Collaborations.** Biora completed additional animal studies during the first quarter that demonstrated performance advances in consistency and bioavailability for the company's peptide candidate, semaglutide, and its antibody candidate, adalimumab, as well as collaborator molecules. The platform continues to exceed its performance target of 15% bioavailability compared to IV administration.

Capital Markets

- **Optimization of Capital Structure.** During the first quarter, Biora secured a third note exchange, bringing total capital raised to $19.8 million in new investment since December 2023, and more than $80 million reduction in notes outstanding through these transactions over the last three quarters, demonstrating continued support from institutional investors.
- **Access to Capital Markets.** During the first quarter, Biora also secured $3 million from the monetization of legacy assets, equity proceeds of $2.9 million, and a $6 million registered direct placement that closed in early April, bringing in a total of $31 million in capital during the past four months.

Anticipated Milestones

NaviCap™ Targeted Oral Delivery Platform and BT-600 in ulcerative colitis

- Biora expects to receive final SAD/MAD data during Q2 2024 and plans to present topline data from the clinical trial toward the end of the second quarter.
- The company will present clinical data on the function of the NaviCap device across four different studies in healthy human participants and active UC patients at the Digestive Disease Week (DDW) conference on May 19, 2024.
- Initiation of a clinical study in active ulcerative colitis patients is anticipated during the second half of 2024.

BioJet™ Systemic Oral Delivery Platform development

- An update on data from recent animal studies will be shared at the Next Gen Peptide Formulation & Delivery Summit in June 2024.

- The company's progress is on track toward a pharma partnership for the BioJet platform in 2024.

First Quarter 2024 Financial Results

Comparison of Three Months Ended March 31, 2024 and December 31, 2023

Operating expenses were $16.1 million for the three months ended March 31, 2024, including $1.5 million in non-cash stock-based compensation expenses, compared to $13.3 million for the three months ended December 31, 2023 including $1.5 million in non-cash stock-based compensation expenses.

Net loss was $4.2 million, net of non-cash items of $13.9 million attributable to the change in fair value of warrant liabilities, while net loss per share was $0.14 for the three months ended March 31, 2024, compared to a net loss of $15.4 million, including non-cash charges of $6.4 million attributable to the convertible notes exchange and $3.0 million impairment on equity investments, while net loss per share was $0.62 for the three months ended December 31, 2023.

Comparison of Three Months Ended March 31, 2024 and 2023

Operating expenses were $16.1 million for the three months ended March 31, 2024, including $1.5 million in non-cash stock-based compensation expenses, compared to $15.5 million for the three months ended March 31, 2023, including $2.4 million in non-cash stock-based compensation expenses.

Net loss was $4.2 million, net of non-cash items of $13.9 million attributable to the change in fair value of warrant liabilities, while net loss per share was $0.14 for the three months ended March 31, 2024, compared to a net loss of $17.4 million and net loss per share of $1.59 for the three months ended March 31, 2023.

Conference Call and Webcast Information

Date:	Wednesday, May 15, 2024
Time:	4:30 PM Eastern time / 1:30 PM Pacific time
Conference Call:	Domestic 1-877-423-9813 International 1-201-689-8573 Conference ID 13746163 Call me for instant telephone access
Webcast:	https://investors.bioratherapeutics.com/events-presentations

About Biora Therapeutics

Biora Therapeutics is reimagining therapeutic delivery. By creating innovative smart pills designed for targeted drug delivery to the GI tract, and systemic, needle-free delivery of biotherapeutics, the company is developing therapies to improve patients' lives.

Biora is focused on development of two therapeutics platforms: the NaviCap™ targeted oral delivery platform, which is designed to improve outcomes for patients with inflammatory bowel disease through treatment at the site of disease in the gastrointestinal tract, and the BioJet™ systemic oral delivery platform, which is designed to replace injection for better management of chronic diseases through needle-free, oral delivery of large molecules.

For more information, visit bioratherapeutics.com or follow the company on LinkedIn or Twitter.

Safe Harbor Statement or Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this press release, including anticipated milestones, statements concerning the progress and future expectations and goals of our research and development, preclinical and clinical trial activities, and partnering and collaboration efforts with third parties, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “anticipate,” “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “forward,” “believe,” “design,” “estimate,” “predict,” “potential,” “plan,” “target,” or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements reflect our plans, estimates, and expectations, as of the date of this press release. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this press release. Such risks, uncertainties, and other factors include, among others, our ability to innovate in the field of therapeutics, our ability to make future FDA filings and initiate and execute clinical trials on expected timelines or at all, our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines or at all, our plans to research, develop, and commercialize new products, the unpredictable relationship between preclinical study results and clinical study results, our expectations regarding allowed patents or intended grants to result in issued or granted patents, our expectations regarding opportunities with current or future pharmaceutical collaborators or partners, our ability to raise sufficient capital to achieve our business objectives, and those risks described in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC and other subsequent documents, including Quarterly Reports, that we file with the SEC.

Biora Therapeutics expressly disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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Biora Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended	
	March 31, 2024	December 31, 2023
Revenues	$ 542	$ —
Operating expenses:		
Research and development	7,005	6,118
Selling, general and administrative	9,053	7,226
Total operating expenses	16,058	13,344
Loss from operations	(15,516)	(13,344)
Interest expense, net	(2,757)	(1,840)
Gain on warrant liabilities	13,915	12,733
Other income (expense), net	217	(13,276)
Loss before income taxes	(4,141)	(15,727)
Income tax expense (benefit)	48	(95)
Loss from continuing operations	(4,189)	(15,632)
Gain from discontinued operations	—	219
Net loss	$ (4,189)	$ (15,413)
Net loss per share from continuing operations, basic and diluted	$ (0.14)	$ (0.63)
Net gain per share from discontinued operations, basic and diluted	$ —	$ 0.01
Net loss per share, basic and diluted	$ (0.14)	$ (0.62)
Weighted average shares outstanding, basic and diluted	29,296,767	24,810,923

Biora Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2024	**2023**
Revenues	$ 542	$ 2
Operating expenses:		
Research and development	7,005	7,190
Selling, general and administrative	9,053	8,356
Total operating expenses	16,058	15,546
Loss from operations	(15,516)	(15,544)
Interest expense, net	(2,757)	(2,680)
Gain on warrant liabilities	13,915	864
Other income (expense), net	217	(81)
Loss before income taxes	(4,141)	(17,441)
Income tax expense	48	—
Net loss	$ (4,189)	$ (17,441)
Net loss per share, basic and diluted	$ (0.14)	$ (1.59)
Weighted average shares outstanding, basic and diluted	29,296,767	10,970,583

Biora Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	March 31, 2024	December 31, 2023 (1)
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	$ 10,820	$ 15,211
Income tax receivable	822	830
Prepaid expenses and other current assets	2,429	3,030
Total current assets	14,071	19,071
Property and equipment, net	1,136	1,156
Right-of-use assets	1,418	1,614
Other assets	293	3,302
Goodwill	6,072	6,072
Total assets	$ 22,990	$ 31,215
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 4,936	$ 2,843
Accrued expenses and other current liabilities	16,984	17,319
Warrant liabilities	27,208	40,834
Related party senior secured convertible notes, current portion	1,976	1,976
Total current liabilities	51,104	62,972
Convertible notes, net	4,497	9,966
Senior secured convertible notes, net	18,709	14,591
Related party senior secured convertible notes, net	20,072	19,179
Derivative liabilities	26,210	22,899
Other long-term liabilities	2,583	3,029
Total liabilities	$ 123,175	$ 132,636
Stockholders' deficit:		
Common stock	28	25
Additional paid-in capital	874,013	868,591
Accumulated deficit	(955,147)	(950,958)
Treasury stock	(19,079)	(19,079)
Total stockholders' deficit	(100,185)	(101,421)
Total liabilities and stockholders' deficit	$ 22,990	$ 31,215

(1) The condensed consolidated balance sheet data as of December 31, 2023 has been derived from the audited consolidated financial statements